

REMARKS

Claims 26-39 are pending in this application. Claims 33-39 were withdrawn from consideration as being directed to a non-elected subject matter. Claims 29 and 31 were rejected under 35 U.S.C. § 112, second paragraph. Claim 26 was rejected under the doctrine of obviousness-type double patenting. Claims 26-30 were variously rejected under 35 U.S.C. § 103.

By this amendment, claims 29 and 31 have been amended without prejudice or disclaimer of any previously claimed subject matter. Support for the amendments can be found, *inter alia*, throughout the specification. The amendments are made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Restriction Requirement

Claims 33-39 were withdrawn from consideration as being directed to a non-elected invention. Applicants respectfully traverse this restriction on the grounds that the Examiner has not provided adequate basis for the restriction of claims into these groups according to M.P.E.P. §806.05. The Examiner has not provided a basis for an undue search burden which is required for a restriction requirement. M.P.E.P. §803. Applicants respectfully submit that these claims present no such undue burden and as such the restriction between claims 33-39 and the other claims may be properly withdrawn. Applicants respectfully request reconsideration and withdrawal of the restriction requirement.

Rejection under 35 U.S.C. §112, second paragraph

Claims 29 and 31 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection.

Although Applicants believe that the claims were sufficiently definite when considered in view of the specification and the understanding of those of skill in the art, Applicants have attempted to respond to the concerns of the Examiner in order to enhance clarity and to facilitate disposition of the present case. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Rejections Under Obviousness-Type Double Patenting

Claim 26 was rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 1 of U.S. Patent No. 5,763,262. As an initial matter, Applicants respectfully point out that previously presented claim 33, which the Office has identified as patentably distinct from presently pending claim 26 and hence has made subject to restriction, is more closely related to claim 1 of U.S. Patent No. 5,763,262 than is presently pending claim 26. None-the-less, Applicants respectfully assert that a terminal disclaimer under 37 C.F.R. 1.321(c) will be provided upon the indication of allowability of the subject matter of claim 26. Accordingly, as this rejection relates to form not necessary for further consideration of the present claims, Applicants respectfully request that the Office hold this requirement in abeyance until allowable relevant subject matter in this application is indicated. -See 37 C.F.R. § 1.111(b).

Rejection under 35 U.S.C. §103

Claims 26-30 were rejected under 35 U.S.C. §103 as allegedly unpatentable over Tom *et al.*, U.S. Patent No. 4,366,241 (*Tom*) in view of Svoboda *et al.*, U.S. Patent No. 4,017,261 (*Svoboda*) and Thomas *et al.*, U.S. Patent No. 4,330,627 (*Thomas*). Applicants respectfully traverse this rejection.

A *prima facie* case of obviousness requires that three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20USPQ2d 1438 (Fed. Cir. 1991); MPEP §2143. If any one of these three criteria is not met, a *prima facie* case of obviousness has not been established. As presented below, Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

In relevant aspect, the presently rejected claims are directed to an immunoassay device having a housing with at least one opening therethrough for introduction of a liquid sample into the housing, a porous matrix material and at least one immunological reagent in dried form in the housing, and a desiccant material in the housing capable of retarding deterioration of the reagent.

The Examiner asserts that in view of *Svoboda*, "one of ordinary skill in the art would have recognized the advantages in placing a desiccant in the device of Tom et al for the purpose of maintaining the viability of the reagents on the test strip by retarding the effects of moisture on the reagents on the test strip." The Examiner also states that "Thomas et al shows how to place a desiccant in an assay device that contains test strips." Office Action, pages 4-5. Applicants respectfully disagree with these assertions.

The primary reference, *Tom*, describes a method and apparatus for performing immunoassays having an immunosorbing zone and a liquid absorbing zone. *Tom*, however, is silent with regard to the desirability of providing a desiccant material in the apparatus, much less with

regard to actually providing a desiccant material in such an apparatus. *Tom* provides no suggestion that moisture even presents a problem to the assays or to immunoassays in general.

Svoboda describes diagnostic test strips designed to segregate the principal components of the test to avoid premature oxidation of a test component. As cited by the Examiner in the previous Office Action,¹ *Svoboda* states that “[i]n order to preclude deterioration prior to use, it has been found useful to store the described test strips in closed containers in the presence of a desiccant such as silica or a molecular sieve.” This statement indicates that the deterioration to be precluded is that of the test strip in general, not necessarily of reagents on the strip and not reagents in a device housing. Based on the *Svoboda* disclosure in its entirety, “closed containers” appears to refer to containers holding more than one test strip, for example, such as a packaging container from which a test strip is removed prior to use. There is no indication or suggestion of an assay housing or device. Thus, neither this statement of *Svoboda* nor any other aspect of *Svoboda* teaches or suggests the test strips in a housing, much less test strips in a housing with desiccant capable of retarding deterioration of a reagent comprised within or on such test strip.

Thomas describes a testing tray for the purpose of biochemical identification of microorganisms. The tray contains a chamber into which a desiccant may be placed to extract undesired moisture from the test channels of the tray. *Thomas* only describes the use of a desiccant to remove condensate moisture from the test channels to allow for proper fluid flow in the channels. *Thomas* does not teach or suggest an immunoassay device nor the use of a desiccant material to retard deterioration of any reagent, much less an immunological reagent.

Accordingly, Applicants maintain that there is no motivation to combine *Tom* with *Svoboda* and *Thomas* for the reasons already of record. Applicants also maintain that there is no suggestion in the references that the teachings therein be modified to arrive at the claimed invention. The

¹ See, Office Action, mailed July 23, 2003, page 5; *Svoboda*, column 4, lines 56-59.

attempted combination with *Svoboda* and *Thomas* fails in that *Tom* denies the presence of moisture as a problem, thus one of skill in the art would not have been motivated to look to *Thomas* or *Svoboda* for guidance.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Applicants submit that only with the disclosure of the present specification that the skilled person would have become motivated to explore the use of a desiccant material capable of retarding deterioration of the immunological reagent as claimed.

Based on the discussion herein, Applicants submit that, even if combined, the references do not teach or suggest an immunoassay device having a housing, a porous matrix material, at least one immunological reagent in dried form in the housing, and a desiccant material in the housing capable of retarding deterioration of the reagent as claimed.

Further Applicants respectfully submit that, even if combined, the references do not provide a skilled artisan an expectation of success for the claimed device. *Tom* provides no indication about how its devices should be modified to successfully incorporate a desiccant. Applicants submit that the required modification would be considerable to maintain the requisite fluid flow characteristics of the device, even if a suggestion to incorporate a desiccant within the enclosure of *Tom* were provided. As such, given the required characteristics of *Tom*'s devices, there is no teaching of how one of skill in the art would adapt these devices to incorporate a desiccant such that deterioration of an immunological reagent would be retarded.

Thus, the cited references do not render the claimed invention obvious and a *prima facie* case of obviousness has not been established.

Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 273102008104.

Dated: October 20, 2004

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